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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/744,804	06/20/2001	Lea Eisenbach	EISENBACH 3	6094

1444 7590 06/19/2003

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EXAMINER

YU, MISOOK

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 06/19/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/744,804

Applicant(s)

EISENBACH ET AL.

Examiner

MISOOK YU, Ph.D.

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 March 2003 and 03 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 16, 19-21, 23, 24, 26-34, 44, 45 and 52-57 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 16, 19-21, 23, 24, 26-34, 44, 45 and 52-57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 13. 6) ☐ Other: _____

DETAILED ACTION

Claims 1, 16, 19-21, 23, 24, 26-34, 44, 45, and 52-57 are pending and examined.

Claim Objections

Claim 52 remains objected to because of the following informalities: the claims have not been amended to reflect the elected invention. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The rejection of claims under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is either **withdrawn or moot**.

Claim Rejections - 35 USC § 112

Rejection of claim 23 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is **withdrawn** because applicant argument is persuasive

Claims 26-29, and 32-34 **remain** rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant argues that the specification teaches several peptides with high affinity for HLA-A2, all peptides bind well as shown at Fig. 13, have good immuogenicity as shown at Fig. 14, and induce CTL as shown at Fig. 15. These arguments are not commensurate in scope of the claims because the claims are drawn to peptides capable of treating cancer. Applicant further argues that CTLs have activity against breast cancer and the publication by Carmon et al shows that BA-46 stimulated CTLs reduce tumor growth. These arguments are not persuasive because applicant argues with the limitation, i.e.,

CTLs, not in the claims. Applicant is reminded that the elected invention is peptides, not CTLs. They are different products.

Claims 1, 19, 20, 21, 23, 24, 26-34, 44, 45, and 52 remain rejected and the new claims 53 and 54 are also rejected for reason of record under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Rejection of claim 16 is withdrawn because the claim is drawn to SEQ ID NO:35-41. Applicant argues that Figs instant Figs. 13-17 as well as Carmon et al teach peptide motif recognized by HLA-A21. However, this argument is not commensurate in scope of claims 1, 19, 20, 21, 23, 44, and 52 because these claims are interpreted as drawn to any 10 or 9 contiguous peptides from Lactadherin (BA-46), not limited to those peptides shown at the figures or the publication and also the claims are not limited to the specific MHC class I type the specification an/or the publication show enabling. Applicant further argues that CTLs made from the peptides reduce tumor volume but this argument is not convincing either because applicant argues with the limitation not present in the claims. Applicant's invention is pharmaceutical comprising peptides as its main active ingredient. The specification or the mentioned publication does not show any in vivo data showing that tumor volume is decreased when peptides are administered to in vivo model.

REJECTION UNDER 35 USC 112, FIRST PARAGRAPH, SCOPE

Claims 1, 19, 20, 21, 23, 24, 26-34, 44, 45, 52 remain rejected and the new claims 53 and 54 are also rejected for reason of record under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID NOs: 35-41 being able to complex with HLA-A2, does not reasonably provide enablement for any other Lactadherin-derived peptide fragments capable of specifically being associated with any other MHC molecule. Applicant argues that it is routine to screen which 9- or 10-mer peptides bind to which MHC but this argument is not persuasive because Carmon et al (2002) well after the effective filing date of the instant application say that it

requires a large quantity of experimentation to determine which peptide work with which MHC.

Claim Rejections - 35 USC § 102

The rejection of the claims under 35 U.S.C. 102(b) as being anticipated by any of US Pat. 5,455,031 (October 3, 1995), WO 95/15171 (June 8, 1995), or Larocca et al (1991, Cancer Res. 51; 4994-4998) is withdrawn because the Office interprets the amended claims are no longer drawn to the full length Lactadherin (BA-46).

NEW GROUNDS OF REJECTION

Claim Rejections - 35 USC § 112

Claims 1, 19, 20, 21, 23, 24, 26-34, 44, 45, and 53-57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is confusing for two reasons. First, the terminology "nona or "deca" is used in the art to indicate how many carbons are present in a molecule according to McMurry, J (1988, Organic Chemistry, page 65 only) and the specification does not teach applicant's own terminology. Second, the dependent claims 21 and 23 makes the base claim confusing because the base claim appears to drawn to peptides consisting of 9 or 10 contiguous amino acids of Lactaherin but the dependent claims say otherwise. This rejection affects all the dependent claims.

Claim 16 recites "41 or 41" in line 2 but it is not clear what the metes and bounds are.

Allowable Subject Matter

Peptides consisting of SEQ ID NOs 35-41 are free of art.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 703-308-2454. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Misook Yu

Misook Yu

June 14, 2003